Office Action Summary	Application No.	Applicant(s)	
	10/506,728	BORODY ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,37-40 and 42-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,37-40 and 42-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *9/29/2010*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed July 23, 2010. Claims 1-11, 37-40, and 42-57 are pending in the application. Claims 54-57 are newly Claims 1-11, 37-40, and 42-57 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant does not have support for the term, mannitol, as a minimally degradable sugar. Applicant amended the specification on March 15, 2010 to delete the terms, mannitol and lactulose, from the listing of degradable sugars, however, Applicant did not add the terms back to the specification as a minimally degradable sugar, as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 37-40, and 42-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims are drawn to a purgative composition comprising at least one water-soluble sodium salt; at least on water-soluble "minimally" degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt within specific claim ranges. In view of University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886, (U.S. Court of Appeals Federal Circuit, 2004), the claim does not identify any compound or provide evidence that those skilled in the art could identify compounds based on the claim's vague functional description, "minimally" degradable sugar. At best, it simply indicates that one should run tests on a wide spectrum of sugars in the hope that at least one of the many possible "minimally" degradable sugars will provide the desired functional limitations. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties,* (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function,* and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discusses on page 7, lines 29-30, the term, "minimally degradable sugar" is to be understood to mean a carbohydrate moiety that is substantially resistant to endogenous digestion in the gastrointestinal tract.

The claims are drawn to a purgative composition comprising at least one water-soluble sodium salt; at least on water-soluble "minimally" degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt within specific claim ranges.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claims indicates that these claims are drawn to any "minimally" degradable sugar that is substantially resistant to endogenous digestion in the gastrointestinal tract. There are only a few species explicitly disclosed, see claim 2 and page 7, lines 31-34.

The disclosure of the disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses any sugar that is "minimally" degradable, without defining the metes and bounds of "minimally". Defining the composition in functional terms would not suffice in the absence of a disclosure of structural features or elements of the sugar that would have the stated function. Applicant is describing what the composition does rather than what it is. Describing a compound by its functions will not substitute for written description of the structure of the compound. The invention should be explained in such a way as to describe what the invention is, not what the invention does.

Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of "minimally" degradable sugars may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification does not disclose the common structural feature shared by the members of the claimed genus. Since the claimed genus encompasses "minimally" degradable sugars yet to be discovered, the disclosed undisclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of "minimally" degradable sugars does not provide an adequate description of the claimed genus.

Weighing all the factors, the breadth of the claims reading on compositions yet to be discovered, the lack of correlation between structure and function of the compositions, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of

"minimally" degradable sugars. At best, it simply indicates that one should run tests on a wide spectrum of degradable sugars in the hope that at least one of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms that are common to the genus. That is, the specification provides neither a representative number of "minimally" degradable sugars to describe the claimed genus, nor does it provide a description of structural features that are common to the "minimally" degradable sugars. In essence, the specification simply directs those skilled in the art to go figure out for themselves the structure of the claimed "minimally" degradable sugars.

The written description requirement is not satisfied.

Claims 54-57are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter introduced, "mannitol" lacks written description as originally filed as a minimally degradable sugar. Applicant amended the specification on March 15, 2010 to delete the terms, mannitol and lactulose, from the listing of degradable sugars, however, Applicant did not add the terms back to the specification as a minimally degradable sugar, as claimed.

Claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant claims the water soluble minimally degradable sugar comprises mannitol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims 54-57are drawn to a purgative composition comprising at least one water-soluble sodium salt; at least on water-soluble minimally degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt within specific claim ranges. The minimally degradable sugar comprises mannitol.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdAPIs 1986) at 547 the court recited eight factors:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The instant invention pertains to a purgative composition comprising at least one water-soluble sodium salt; at least on water-soluble minimally degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt within specific claim ranges, wherein the minimally degradable sugar comprises mannitol.

State of the art: The skilled artisan would view that the use of mannitol in a purgative composition containing is highly unlikely. Based on the teachings of The Schiller Publication (2001), the use of lactulose and other fermentable substrates should not be used in colon preparations because of the risk of producing hydrogen gas in explosive concentrations in the colon (page 759, col. 1, 2nd paragraph). Schiller teaches that sorbitol and mannitol are sugar alcohols that, like lactulose, are poorly absorbed by the small intestines and they share a propensity to produce abdominal distention and flatus due to gas production (page 753, col. 2, paragraph 3). Kawakami, JP 05306211, teaches that mannitol is not used in purgative compositions due to the hydrogen and methane gas produced by the decomposition of mannitol by the bacteria in the intestines and the possible explosion of the intestines during operations due to these gases (paragraph 5).

Relative skill of those in the art: The relative skill of those in the art is high, typically requiring an advanced professional degree.

Predictability or lack thereof in the art: The skilled artisan would view that the use of mannitol in purgative compositions is highly unpredictable.

Amount of guidance provided by the inventor and existence of working examples:

In the instant case, 6 working examples are provided in the specification as filed showing how to formulate the purgative compositions. No working examples are provided with the use of mannitol as the minimally degradable sugar. All of the working examples use xylose as the minimally degradable sugar. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP §2164.

> Genetech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable.

Therefore, in view of the ***Wands*** factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to produce a purgative composition wherein mannitol is the minimally degradable sugar.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 37-40, and 42-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims a purgative composition that comprises at least one water-soluble sodium salt; at least on water-soluble "minimally" degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt within specific claim ranges. Applicant has not defined the metes and bounds of the term, minimally, in reference to the degradable sugar. Applicant has defined a "minimally" degradable sugar as a carbohydrate moiety

that is substantially resistant to endogenous digestion in the gastrointestinal tract, however, Applicant has not defined what perimeters are used to measure the degradability of a sugar that would make it minimally degraded. One skilled in the art may define "minimally" as 1% degraded, while another skilled artisan may define "minimally" as 5% degraded. Applicant should define metes and bounds of "minimally" within the claims.

None of the claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Johann R. Richter/
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